NATIONAL BLOOD AUTHORITY
AUSTRALIA

Monitoring International Trends

August-September 2021

The NBA monitors international developments that may influence the management of blood and blood products in Australia including but not limited to:

- Potential new product developments and applications
- Global regulatory and blood practice trends
- Events that may have an impact on global supply, demand and pricing
- Emerging risks and relevant issues.

Some key topics that have appeared in news media, online publications, and industry and research updates have been included in this report, including:

- **Blood Supply:** Calls for blood donations continue internationally as COVID-19 affects blood supplies with extreme shortages in the United States (US). Efforts are underway across the US and United Kingdom (UK) to recruit more diverse donors to ensure sickle cell disease patients can find matches. An inquiry into infected blood is underway in the UK. Changes have been made to the blood donation criteria for gay men in Australia and the Canada.
- **Blood Disorders:** Research continues for vaccine-induced immune thrombotic thrombocytopenia (VITT) with the risk of VITT declining, within weeks after initial diagnoses. Among this month's report is also news about haemophilia, anaemia, sickle cell disease, and several blood cancers.
- **Transfusion:** Calls are being made for a common definition for the term *massive transfusion.* There are reports about existing trials in blood product usage and how wastage can be reduced.
- **Gene Therapy**: Bio-tech company, Bluebird, has officially asked the US Food and Drug Administration (FDA) to approve their therapy for beta-thalassemia. The FDA approved a fast-tracked treatment for relapsed multiple myeloma. Gene therapy trials are also underway for haemophilia and sickle cell disease.
- **COVID-19:** The effects of the virus are being felt across the blood sector, including on blood collection and hospitalisations. As vaccination numbers increase, the focus of research and treatment options is turning to the management of the unvaccinated and immunocompromised.
- **Other items of interest:** Europe is looking to rewrite its 'pharma' legislation to promote breakthroughs in areas of unmet need. The UK has opened consultation on the scope of current regulation of medical devices.

NATIONAL BLOOD AUTHORITY
AUSTRALIA

Contents

1 Blood supply

This section contains news articles and government agency statements on blood supply, changes to donation criteria as well as reports from the UK Infected Blood inquiry.

Blood shortages: United States and Canada

US Blood centres launch Nation's first emergency blood reserve Blood shortages across the US continue with states working together to collect across regions, in response to the scarcity brought by COVID-19.

USA Blood Products Availability Weather events have also disrupted airline deliveries of blood in the US.

USA: Supply Report This US report estimated nationwide average supply of approximately 2.3 days for O-negative, 2.2 days for O-positive red blood cells, with moderate availability of A-positive red blood cells and slow improvements in the availability of B-positive and A-negative.

American Red Cross in the middle of emergency blood shortage The American Red Cross advised that it needed 10,000 blood products every week for the month of September to catch up on short supply, especially for type "O" blood. The Red Cross said supply has not been this low since 2015.

US Red Cross launches national initiative to reach more blood donors to help patients with sickle cell disease The American Red Cross launched a specific campaign to reach more blood donors who are of African American decent to help patients with sickle cell disease and improve health outcomes.

Blood shortages planning in Canada: The National Emergency Blood Management Committee experience during the first 6 months of the COVID-19 pandemic PDF of report available at link.

Changes to donation criteria

A Massive Change Means It's Finally Much Easier for Queer Men to Donate Plasma in Australia As of August 2021, the TGA has approved the submission, and queer men can donate plasma (but not blood) after three months without PrEP (HIV prevention drug) reduced from 12 months.

Trudeau says he expects end soon to blood donation ban for gay, bisexual men Canada introduced a lifetime ban for gay men in 1992 and in 2013 changed their policy to accept blood donations from men who have abstained from sex with another man for at least five years. This was changed to three months in 2019.

Blood donors in the UK can now give plasma to be used for lifesaving treatment The UK has been relying on imported immunoglobulin, but UK donors will now be able to donate plasma for immunoglobulin.

Blood and plasma donation: Australia and New Zealand

CSL CEO: Pace of Plasma Collections Expected to Exceed Pre-COVID-19 Levels Around December CSL Behring reported that plasma collection fell 20% in the 2021 fiscal year, and the manufacturing of raw plasma into immunoglobulin can take months so it is expected to impact 2022 financial year also.

Blood 2021: Pandemic challenged but failed to interrupt blood supply NBA reported to Blood 2021 Conference that there has been no need to activate the National Blood Supply Contingency Plan. In 2020, demand for fresh blood product was down and supply was up when elective surgery was first cancelled, this situation has now flipped in 2021 with demand for red cells at a 10-year high.

Can you donate blood in lockdown? - Canberra Lifeblood continues to encourage Australians to donate blood during lockdown.

NZ Blood Service needs more donors in Timaru to meet target Despite exceeding expectations in last few days, unless more people donate NZ Blood Service say they will not meet their target.

Infected blood inquiry: United Kingdom

UK former Conservative health secretary has said loss of life could have been avoided in the tainted blood scandal Former Conservative health secretary, Norman Fowler, has said lives could have been saved if the UK had stopped importing blood products from overseas including countries like the US and Australia prior to 1981.

UK contaminated blood scandal In the UK up to 30,000 people were treated with contaminated blood from overseas including Australia. In 1996, Commonwealth Serum Laboratories (CSL) which was owned by the Australian federal government until 1994, admitted it previously mixed Australian blood with blood from countries throughout the Pacific. This story raises uncertainly on contaminated blood from Australian sourced blood products between the 1970s and early 1990s.

Supply chain issues: United Kingdom

UK: Supply chain crisis could last month's PM admits, but fuel situation 'improving' There are concerns about delivery of blood products to hospitals due to fuel shortages.

NHS blood tube shortage: Supplier ramps up imports In late August 2021, imports of blood test vials for the NHS were increased to alleviate shortages while production capacity has been increased locally by 20%. Doctors were told to stop most blood tests until 17 September.

Other items

Secondary Education in UK now includes learning about blood, organ and stem cell donation New curriculum in United Kingdom includes resources to help teachers educate secondary students about the different kinds of donations and difference they can make. Officials hope young people will consider becoming donors and drive donation conversations at home.

Bangladesh blood banks scramble for platelets as dengue cases rise Bangladesh has seen significant spike in dengue fever with 15,976 cases and 59 deaths so far this year. This has created a huge rush of blood use by dengue patients with critically low platelets.

2 Blood disorders and treatments

This section includes published research and industry statements on the progress of blood disorder treatments across various conditions.

2.1 Vaccine-induced immune thrombotic thrombocytopenia (VITT)

Risk of VITT-related thrombosis declines within weeks A German study indicates risk of thrombosis in most patients who have developed VITT appears to decline within three months. More than 90% of VITT patients' pathologic, platelet-activating anti-PF4 antibodies had disappeared by the 12-week mark.

Successful venous thromboprophylaxis in a patient with VITT: the first reported case in Thailand A first documented case of VITT in a non-Caucasian population, treated successfully with intravenous immunoglobulin, high-dose dexamethasone and prophylactic dose of apixaban.

Two Flags for Poor Prognosis After Rare VITT With AstraZeneca Jab In August two factors were identified by British doctors as dramatically increasing the likelihood of a patient dying following rare side effects of VITT. These factors are very low platelet counts and brain bleeds.

Thromboprophylaxis could help minimise VTE risk in hospitalised COVID-19 patients An Australian hospital in Victoria has helped minimise VTE rates in hospitalised COVID-19 patients via a risk-adapted prophylaxis protocol.

Buyer beware: The risks of donor-derived vaccine-induced thrombosis and thrombocytopenia For organ transplants, a question has arisen about whether it is safe to accept organs donated by someone who died of VITT.

2.2 Haemophilia

Breakthrough Bleeds Likely for Haemophilia A Patients on Hemlibra, Study Finds Despite preventative therapy with emicizumab (Hemlibra), this study found the risk of bleeding persists with most patients experiencing spontaneous or traumatic bleeds at some point. Results indicated the risk of spontaneous bleeds is higher for older individuals.

Severe acquired haemophilia associated with asymptomatic COVID-19 infection *and* COVID-19 Infection May Trigger Acquired Haemophilia A This case study suggested that the COVID-19 virus may have triggered acquired haemophilia A.

Haemophilia A and C identified in a 17-year-old female: The first case report in literature The first recorded case in a female of haemophilia A and C has been identified. The challenge in this case has been to treat combined coagulation factors deficiencies.

2.3 Anaemia

Tackling Anaemia Through Fortified Rice: A Pilot Programme Shows Promise in India Iron deficiency is the most common cause of anaemia developing. There is a pilot intervention underway in India focused on rice fortification with iron to combat the issue.

Reducing Anaemia in Pregnancy in India— randomized-controlled trial comparing the effectiveness of treatments of iron deficiency anaemia in pregnant women A trial is set to provide evidence to determine if single-dose intravenous iron infusion is more effective and economically feasible in reducing iron deficiency anaemia in pregnancy. This is in comparison to the current standard of care of oral iron supplements.

Anaemia May Increase Risks of Ischemic Stroke and Poststroke Mortality In South Korea an analysis of insurance claims data suggested an increased risk of post-stroke mortality in anaemic patients.

Intravenous immunoglobulin (IVIG)Therapy May Fight Parvovirus-Associated Pure Red Cell Aplasia This study shows that IVIg therapy may help combat parvovirus in individuals with anaemia.

2.4 Sickle cell disease

U.S. FDA accepts priority review supplemental new drug application for Oxbryta® (voxelotor) for the treatment of Sickle Cell Disease in children ages 4 to 11 FDA granted priority review for the new drug application for Oxbryta. Oxbryta is an oral drug that improves haemoglobin affinity for oxygen.

Sickle cell, dengue creating serious complications in young patients in India A report from early September 2021 states that sickle cell patients are getting infected with dengue in large numbers.

2.5 Blood cancers

Royal College of Pathologists of Australasia have submitted a next generation sequencing panel for the molecular characterisation of haematological malignancies to the Australian Medical Service Advisory Committee Haematological malignancy is relatively common as a group of disorders, constituting approximately 9% of all cancer cases diagnosed annually. The application is a request for Medicare Benefits Scheme (MBS) funding as a new item.

Janssen Australia and New Zealand have submitted a highly specialised therapy for Multiple Myeloma to the Australian Medical Services Advisory Committee Ciltacabtagene autoleucel is a chimeric antigen receptor T (CAR-T) cell therapy. It can treat patients with multiple myeloma that is refractory, or for those who have failed more than three lines of prior therapy. The therapy involves taking the patient's own cells from peripheral blood, enriching them for T-cells and genetically modifying them before infusing them back into the patient to treat multiple myeloma.

Legend Biotech begins phase 1 clinical trial in the US to evaluate investigational anti-CD4 CAR-T therapy for relapsed or refractory T-Cell lymphoma Announcement of the start of a Phase 1 clinical trial in the US for LB1901, an investigational autologous CD4-targeted chimeric antigen receptor T-cell (CAR-T) therapy for the treatment of adults with relapsed or refractory peripheral T-cell lymphoma or cutaneous T-cell lymphoma.

Dose escalation of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin lymphoma: an open-label, phase 1/2 study Research is underway to establish the safety and recommended phase 2 dose of epcoritamab, a novel bispecific antibody.

Open-label, randomised, phase 3 trial of daratumumab for patients with newly diagnosed multiple myeloma Research has found maintenance with daratumumab, a targeted monoclonal antibody, every 8 weeks for 2 years significantly reduced the risk of disease progression or death compared with observation only.

Podcast: Perspectives on the use of ibrutinib for relapsed/refractory mantle cell lymphoma Professor Martin Dreyling (Germany) provides insights into the clinical implications of the 7.5-year follow-up data for ibrutinib and how he approaches these discussions with patients.

Podcast: Long-term data and patient priorities inform relapsed or refractory chronic lymphocytic leukaemia (CLL) management Professor Susan O'Brien explains how long-term data and patient priorities are both key considerations when considering treatment approaches for her relapsed or refractory CLL patients.

Four years on: what to expect for CLL treated with acalabrutinib-backed therapy Data presented at the Haematology Association in June 2021 for the treatment of CLL showed acalabrutinib maintains efficacy and safety at four years post treatment

Blood cancer patients 'at risk' as Australian Bone Marrow Donor Registry pleads for funds The future for life-saving stem cell and bone marrow transplants is looking grim amid acute COVID-19 disruptions and a funding crunch.

2.6 Immune thrombocytopenia

Corticosteroid treatment for Primary immune thrombocytopenia (ITP) Primary ITP is an acquired autoimmune disorder which increases patient bleeding risk. Corticosteroids are standard first line treatment, but 80% of adult patients will experience treatment failure or become dependent and require second line therapy.

Immune thrombocytopenia: earlier use of mycophenolate mofetil boosts ITP treatment outcomes UK research has shown adding mycophenolate mofetil to a glucocorticoid for first-line treatment of immune thrombocytopenia (an autoimmune bleeding disorder) improved treatment response and cut the risk for refractory or relapsed disease.

2.7 Other

BioCryst's Hereditary angioedema medicine Orladeyo wins NICE nod Orladeyo, for the prevention of recurrent attacks of hereditary angioedema (HAE) in people age 12 years and older, has received a positive recommendation from the UK National Institute for Health and Care excellence (NICE).

Accelerated approval haematology drugs are slow to confirm benefits Some blood cancer drugs are given accelerated approval by the US FDA and subsequently fail to demonstrate benefit in confirmation post-approval trials but remain approved regardless.

Effect of tranexamic acid by baseline risk of death in acute bleeding patients: a meta-analysis of individual patient-level data from a large sample Researchers found no increased risk of vascular occlusive events with treatment of tranexamic acid and it did not vary by baseline risk categories.

Early transition to direct oral anticoagulant (DOAC) after pulmonary embolism (PE) appears safe Researchers say that an early switch to a DOAC from heparin after PE can be safe in adults.

European Commission approves Ultomiris for children and adolescents with paroxysmal nocturnal haemoglobinuria (PNH) The European Commission has approved AstraZeneca's Ultomiris (ravulizumab), used to treat PNH, for expanded use in the EU to include children with the condition and a body weight of 10kg or more.

Effect of a factor-based coagulation management on blood product use after major burn injury: A retrospective cohort study Research investigated the impacts of a goal-directed and factor-based coagulation algorithm on blood product use and clinical outcomes in severely burned patients. Researchers found treatment of this cohort with goal-directed coagulation algorithym reduced blood product use and resulted in target oriented administration of coagulation factors that improved outcomes.

New Data-sharing Program Aims to Accelerate Rare Disease Innovation An FDA funded, US initiative called Rare Disease Cures Accelerator-Data and Analytics Platform includes rare disease data from clinical trials, observational studies, patient registries and real world data. The platform aims to promote the standardisation of new data collection.

3 Transfusion

This section includes published research and industry publications on transfusion procedures to improve patient outcomes and reduced wastage of blood products.

Epidemiology of massive transfusion – a common intervention in need of a definition Monash University authors call for a clear definition of massive transfusion (MT) as this patient group accounts for approximately 10% of blood product issues in hospital-based studies.

Four-factor prothrombin complex concentrate to reduce allogenic blood product transfusion in patients with major trauma Researchers hypothesising that four-factor prothrombin complex concentrate in addition to a massive transfusion protocol decreases blood product consumption at day one in severe trauma patients with major bleeding. The trial started in 2017 with enrolment expected to be complete by June 2021.

Effects of rotational thromboelastometry (ROTEM) – guided transfusion management in patients undergoing surgical intervention for postpartum haemorrhage (PPH) The introduction of ROTEM-guided transfusion did not reduce packed red blood cells (PRBC) transfusion in patients with PPH treated in the operating theatre but did reduce the need for platelet or Fresh Frozen Plasma transfusion.

Single versus multiple unit transfusion in hemodynamically stable postpartum anaemia: a pragmatic randomised, controlled trial No difference was found in vital signs or symptoms, length of stay, 30-day complications or 4-9-week postpartum outcomes in single or multiple unit transfusions of hemodynamically stable post-partum anaemia patients.

Determining transfusion needs for major burn patients: A retrospective review and analysis This study reviewed the blood product usage trends and associated factors for patients with major burns in a single centre over 10 years.

Hypoxic storage of red blood cells improves metabolism and post-transfusion recovery Authors found that hypoxic storage (oxygen not available) of red blood cells resulted in improved post-transfusion recoveries in healthy recipients. Research has been awarded a Research Innovation in Scientific Excellence (RISE) award by the Association for the Advancement of Blood and Biotherapies.

4 Gene therapies

This section includes industry updates on the progress of gene therapies though regulatory bodies as well as gene therapy safety.

4.1 Blood related gene therapies

Bluebird officially asks FDA to approve gene therapy for rare blood disorder Beti-cel gene therapy has been tested in multiple early and late-stage clinical trials as a one-time treatment for beta-thalassemia, a rare condition impairing the production of haemoglobin in red blood cells. The therapy has already been cleared for market in Europe where it is sold as Zynteglo.

Role of Gene Therapy in Sickle Cell Disease Recording (video) of shared insights about the safety profile and cost of gene therapy for the management of sickle cell disease as a point mutation. Includes discussion of the Bluebird therapy trial.

ALLO-605 Receives FDA Fast Track Designation for Relapsed/Refractory multiple myeloma ALLO-605 is an allogeneic, gene-edited, BCMA-directed CAR T-cell therapy. Phase I trial evaluating safety, feasibility and recommended phase II dose has begun enrolling patients with relapsed or refractory multiple myeloma.

FDA clears Investigational New Drug application for CRISPR-edited T-cell receptor therapy to treat Acute myeloid leukemia With enrolment scheduled to begin by the end of the year, this multi-arm phase trial will evaluate the safety, tolerability, cell kinetics and antitumor activity of a single dose.

Gene therapy for haemophilia: a review on clinical benefit, limitations, and remaining issues This review paper summarises the most recent findings of reported and ongoing gene therapy trials with a focus on recent haemophilia A and B trials.

4.2 Regulatory progress

Building a bridge of equivalence to facilitate and implement rapid process changes in gene therapy manufacturing The gene therapy market is expanding globally at approximately 30% annually. A current challenge is no clear regulatory path for establishing equivalency of gene therapy manufacturing processes, this limits greater progress toward more cost-effective treatments.

Whitepaper: Streamlining and Standardizing Cell and Gene Therapies from Process to Product This paper is produced by Aldevron. The company develops and manufactures plasmid DNA for use in research and clinical laboratories, engaged in gene and cell therapy.

4.3 Non-blood related

Worrisome side effects lead Pfizer to narrow Duchenne gene therapy trial Pfizer plans to change the design of a late-stage gene therapy for Duchenne muscular dystrophy after three patients recently experienced serious side effects involving muscle weakness.

After long wait, Editas reveals first data for CRISPR gene editing treatment Data set to be presented in October offers some hopeful signs for an inherited form of vision loss.

Pfizer backs a small Swiss upstart's attempt to discover a non-viral gene therapy Backed by Pfizer's venture arm, promising DNA-based vector research does not trigger an immune response that the Adeno-Associated Virus (AAV) vectors otherwise used for gene therapy have been known to do.

5 COVID-19

This section contains news articles, peer reviewed papers and industry publications on the changing COVID-19 pandemic across the world including effects on blood and related services.

5.1 COVID-19 effect on blood and related services

CSL Statement on Positive COVID-19 Case at Broadmeadows A confirmed positive COVID-19 case was at the Broadmeadows manufacturing facility in September. All that were present at the time have been tracked and contact tracing has occurred, a deep clean undertaken and the facility is operating as usual with no interruption to production at this site or at the Parkville AstraZeneca vaccine production site.

Canadian Blood Services requires employees to be vaccinated against COVID-19 Canadian Blood services in all provinces and territories except Quebec has stated it will require all employees, volunteers and contractors to be fully vaccinated against COVID-19 or face termination.

Convalescent plasma does not reduce risk of intubation or death for COVID-19 hospitalized patients *and* Large Study Finds Convalescent Plasma Doesn't Help Seriously Ill COVID-19 Patients It had been thought that the blood plasma of COVID-19 survivors would help patients seriously ill from COVID-19, new findings conclude this is not the case.

No evidence of COVID-19 transmission through transfusion of human blood products: A systematic review There is a theoretical risk of transmission of COVID-19 through transfusion however there is limited evidence of transfusion transmission of COVID-19 via human blood products.

5.2 Managing the pandemic

Drug to protect 10% who don't respond to COVID-19 vaccine could soon be available on NHS For the 5-10% of fully vaccinated people in the UK who may still become severely unwell with COVID-19, mainly those with weakened immune systems, new monoclonal antibodies will be made available on the NHS. These monoclonal antibodies are already in use in US, Europe and Asia.

Blood study may show how widely COVID-19 circulated before first Irish case confirmed Samples of donations in Ireland are expected to reveal how widely COVID-19 had circulated in months before the first case was confirmed.

Why llamas could hold the key to preventing future COVID variants Researchers behind clinical trials from a Belgian start-up have said antibodies from a llama reduced the severity of COVID-19 infections during a lab test.

COVID Australia: Oz SAGE science lobby group claims NSW ending lockdown will crash intensive care units A science lobby group has modelled NSW ICU beds being full for six weeks over Christmas and almost 1,000 people dying from COVID-19, as reported in The Age newspaper on 13 September 2021.

NZ records 'probable' Pfizer vaccine death In late August, a New Zealand woman died from inflammation of the heart. The death is suspected to be due to a rare side effect from the Pfizer COVID-19 vaccine.

Some advocate unvaccinated should get priority for an effective early COVID-19 treatment Some US officials are urging healthcare providers to put the unvaccinated first as demand for monoclonal antibodies skyrocketed. The Biden administration moved to take over distribution, causing outcry in Southern states that have used the treatment heavily and will likely have to cut back.

US hospitals and ICUs are full of COVID-19 patients, forcing care rationing The states with the worst outbreaks per capita – Tennessee, Kentucky, Alaska, Wyoming and West Virginia – have all set new hospitalization records and have vaccination rates below the US national average.

US Hospital transfusion service operations during the COVID-19 pandemic: Lessons learned from the AABB hospital survey in preparation for the next infectious disease outbreak A survey circulated weekly and biweekly to hospital-based members has revealed 54% reported increased wastage early in pandemic. The principal lesson learned is to plan ahead, stay organized, and carry on in maintaining close communication between hospitals and blood suppliers.

Hospitalization rate for unvaccinated teens 10 times the rate for those vaccinated, CDC says Data from 14 states between June 20 and July 31, 2021 when Delta became the dominant variant in the US showed unvaccinated teens at 10 times the risk of unvaccinated.

Those with weakened immune systems can start getting third COVID shot In the US, third doses are becoming available for those who are unable to make antibodies sufficiently. The FDA approved the additional shot in August 2021.

5.3 COVID-19 research

Influenza vaccine could also help against severe COVID-19 It is unclear why at this stage, but a study conducted before the worldwide rollout of the COVID-19 vaccine has shown the influenza vaccine could help attenuate the adverse effects of COVID-19.

Association of coagulation disturbances with severity of COVID-19: a longitudinal study Research revealed that the hypercoagulability tendency of severe COVID-19 patients was more evident than in those with mild COVID-19 symptoms.

Settling lawsuit, AstraZeneca and European Commission agree on coronavirus vaccine delivery UK-based drug maker fell behind on promise to supply 300 million doses by the end of June. They are now set to reach target of 300 million doses to European nations by March 2022, nine months later than planned.

The continuous evolution of COVID-19 South Africa: a new lineage with rapid accumulation of mutations of concern and global detection In late August, a 'doomsday' COVID-19 variant was detected in South Africa with warnings it was worse than Delta.

Long-lasting immune abnormalities detected in recovered COVID-19 patients Australian research, yet to be peer-reviewed or published, found substantial dysregulation of immune cell numbers strongest at 12 weeks post infection but still evident in most cases of COVID-19 up to six months.

Australian National University (ANU) research finds Indigenous adults at risk of severe illness from COVID-19 if unvaccinated A study from the ANU has reinforced the need for Aboriginal and Torres Strait Islanders to remain a priority group for vaccination.

5.4 Vaccines

Study finds protection against COVID-19 'waning' in fully vaccinated people Researchers found that protection following two doses of the Pfizer/BioNTech jab fell from 88% at one month to 74% at five to six months. A similar decrease was observed for those vaccinated with AstraZeneca.

CSL won't develop COVID vaccine, shifts focus to flu research CSL is focusing on research into new vaccine tech including mRNA influenza vaccines, looking to further boost value of their Seqirus business.

Data Submitted to FDA shows vaccines are safe in 5 to 11-year old's *and* Pfizer says coronavirus vaccine is safe, spurs immune response in children COVID-19 vaccines data has been submitted to the FDA by Pfizer and BioNTech claiming the shot is safe in children aged 5 to 11 years.

Pfizer-BioNTech coronavirus vaccine gets full FDA approval In August 2021, the FDA granted full approval to the Pfizer-BioNTech COVID-19 vaccine.

Coronavirus vaccines are rolling out quickly. Here's where the pipeline stands A summary of COVID-19 vaccines that have made it to market globally, including efficacy information and a detailed summary of each company's approach, supply targets, funding and development timeline.

FDA panel to discuss boosters as Moderna seeks OK for additional shot Moderna started application to FDA for clearance of booster dose for its coronavirus vaccine. The same day FDA announced it will convene advisory committee to discuss Pfizer's submission for the same authorization.

Valneva starts the UK Medicines and Healthcare products Regulatory Agency regulatory process for COVID-19 vaccine Valneva has launched a rolling submission for approval of their COVID-19 vaccine candidate VLA2001 – a whole virus, inactivated, adjuvanted vaccine – the only vaccine of this type currently in trials.

5.5 Other COVID-19 treatments

Antibody cocktail highly effective at preventing COVID-19 An alternative to vaccines, an antibody cocktail developed by AstraZeneca, has been found effective at preventing symptomatic COVID-19 infections.

Successful treatment of COVID-19-related acute respiratory distress syndrome with a rare blood type People with rare blood types, or those who refuse blood transfusion, do not benefit from extracorporeal membrane oxygenation (ECMO), when being treated for COVID-19. ECMO involves pumping blood outside the body to a heart-lung machine that re-oxygenates it and then returns it to the body. Conservative fluid management should be considered for better oxygenation in these cases.

Roche warns of global Actemra shortage as delta variant drives huge spike in demand for COVID-19 patients In August 2021, Roche warned of high demand for their arthritis drug, Actemra as a treatment for COVID-19. Actemra requests were over 400% higher compared to pre-COVID levels, as the drug is used alongside corticosteroids in hospitalised patients.

6 Other items of interest

This section contains general industry and regulator updates as well as developments in non-blood and non-COVID related diseases.

6.1 Industry and R&D news

In bid to attract more R&D innovation, Europe looks to rewrite its pharma legislation To stimulate new breakthroughs, particularly in areas of unmet need, increase the accessibility of drugs across the continent and make the EU pharma system more attractive, Europeans are looking to rewrite pharmaceutical legislation before the end of 2022.

UK Consultation: Scope of the Regulations The UK government has opened consultation on the future regulation of medical devices.

Moderna to collaborate with AbCellera A collaboration to develop therapeutic antibodies for use across multiple undisclosed indications has been formed. An AI-powered antibody discovery platform will be combined with mRNA technology platform in a bid to accelerate the development of mRNA-encoded antibody therapeutics.

AstraZeneca to buy rare disease drug maker Caelum in small deal Light chain amyloidosis is caused by defective plasma cells, resulting in misfolded proteins that can build up in organs and cause organ failure or death. The drug CAEL-101, developed by Caelum, is an antibody that binds to the misfolded proteins and holds promise as a new drug. AstraZeneca is intending to buy the rare disease drug maker Caelum.

Pfizer UK and Entia partner on home blood monitoring device for breast cancer patients Home blood monitoring devices for NHS metastatic breast cancer clinics will enable patients to perform their own blood test and healthcare teams to remotely monitor results. The required regulatory approvals are expected for UK and EU in early 2022.

6.2 Other diseases and developments of interest

New Mechanism Underlying Red Blood Cell Aging Revealed A study has found an important biophysical mechanism underlying red blood cell aging in which deprivation in oxygen can lead to mechanical degradation of the red blood cell membrane.

Flu vaccine candidate may provide universal protection against influenza strains Researchers say this flu vaccine candidate offers protection against an unprecedented range of swine flu strains.

Study finds biomarker for a disease caused by bone marrow transplant Researchers found a consistent elevation of a specific acid molecule in the blood of patients before and during the onset of chronic graft versus host disease. This acid is the single most significant metabolite associated with the disease.

Analysis of 2021 Ebola outbreak reveals long-term dormant infections The Ebola virus may hide in apparently healthy survivors and trigger new outbreaks years later according to a genomic study.

Ebola Vaccine Effective in African Clinical Trial A study has found two doses of the Johnson & Johnson Ebola vaccine are safe, well tolerated and produce a strong immune response in people over the age of one.

Uptick in dengue cases: 3,200 people hospitalized in 10 days Dhaka remains a hotspot for dengue fever with 253 hospitalisations in a day.

NHS England launches large-scale trial of 'revolutionary' cancer test The NHS England has launched an early stage randomised controlled trial for a blood test to detect of over 50 types of cancer.

The promise and perils of immunotherapy In this review paper, authors highlight the recent advances, and discuss controversies and the future direction for hematologic oncology and blood-related diseases.